

**Proposed Guidance: Pesticides; Plant Biostimulants Guidance; Products and Product
Label Claims
OMB Significance Briefing
September 28, 2017**

Purpose: EPA seeks an OMB non-significant determination on this proposed guidance.

Background: This guidance is intended to identify product label claims that are considered to be plant regulator claims by the Agency, thereby subjecting the products to regulation under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) as pesticides. This document provides examples of both claims that are considered plant regulator claims and claims that are not considered plant regulator claims. This guidance does not address or attempt to provide a regulatory definition for “plant biostimulant” (PBS) or for “nutritional chemical.” However, as part of the public comment period on this draft guidance, the Agency will be seeking input on possible regulatory definitions for these terms. This guidance will not create any new legally binding requirements.

- PBS are a relatively new, but growing category of products.
- Contain naturally-occurring substances and microbes that stimulate plant growth, enhance resistance to plant pests, and reduce abiotic and biotic stress.
- Attractive for use in sustainable agriculture and Integrated Pest Management (IPM) programs.
- Can reduce the use of conventional chemicals.
- One question to consider is whether a product physiologically influences the growth and development of plants in such a way as to be considered plant regulators by the Agency and thereby triggering regulation under FIFRA as a pesticide.
- FIFRA section 2(u) defines plant regulators as pesticides, so they are subject to federal licensing as pesticides under FIFRA.
- Claims for plant regulator activity on the product labels may trigger FIFRA regulation.
- Many of these same substances and products may be excluded or exempt from regulation under FIFRA depending upon their intended uses as plant nutrients (e.g., fertilizers), plant inoculants, soil amendments, and vitamin-hormone products.
- A key consideration is what claims are being made on product labels.
- The proposed guidance includes a discussion of what product claims are and are not considered to be pesticidal based on the existing regulatory framework.
- Will provide needed clarity to the regulated community as well as state regulators.

Benefits/Costs of the Guidance, once Final: This action seeks to eliminate ambiguity and provide regulatory clarity. This lack of clarity may lead some producers to seek federal registrations that might otherwise not be required under FIFRA at a significant cost. Alternatively, a lack of compliance with FIFRA may result from producers’ uncertainty for failing to register a product that is considered a pesticide. The lack of clarity has created a significant burden for federal and state compliance monitoring as inspectors may have difficulty

identifying whether claims listed on product labels are eligible for exclusion from the definition of “plant regulator” and, therefore, excluded from regulation as pesticides under FIFRA. This guidance will provide specificity and clarity concerning label claims that can be on exempted products. EPA has determined that the costs incurred by manufacturers to comply with the proposed guidance are expected to be minimal.

Stakeholder Reactions to Proposed Guidance: Although this guidance has not been issued for public comment, U.S. and international stakeholder response has generally been favorable with the EPA initiative to establish regulatory clarity with the proposed guidance. Numerous meetings and presentations have been held with:

- State and EPA Regional regulators (via the State FIFRA Issues Research and Evaluation Group (SFIREG)).
- Association of American Plant Food Control Officials (AAPFCO).
- U. S. Biostimulants Coalition (USBC).
- Biological Products Industry Alliance (BPIA), as well as with individual plant biostimulant producers.
- Technical presentations before international audiences (such as the annual INFORMA Biostimulants Conferences in Raleigh, NC), including the European Biostimulants Industry Council (EBIC).

Anticipated Reactions from the public: EPA does not anticipate significant interest on the part of the general public. Plant biostimulant products generally consist of non-toxic substances and microbes that are already present in the environment and, as such, adverse human health and environmental impacts are not expected.

Deadline: No deadlines apply to this action.

Milestones: Projected dates:

- OMB non-significance determination – September/October 2017
- Proposed Guidance FRN publishes, November 2017
- Public Comment period – 60 days
- Final guidance publication, June 2018